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CDC
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To Whom It May Concern:

This letter is written to comment on the current draft of the CDC's *Guidelines for the Prevention of Intravascular Catheter-Related Infections*.

My name is Guy D. LaRue and I have been an intravenous nurse for over 20 years. I have placed approximately 20,000 intravenous catheter devices. Most of these intravenous devices were midline catheters, midclavicular catheters and PICCs. I also place short peripheral catheters and occasionally internal jugular catheters. I have placed numerous types and brands of catheters. I have placed these catheters in numerous situations including; patients in seizure, patients being resuscitated, patients in wheelchairs, patients in prison, neonates in cribs, patients in their own beds at home, patients in surgery, and patients in wheelchairs or reclining chairs. I own and manage Precision Vascular Services LLC, which has provided intravenous access services to over 40 healthcare facilities during the last seven years. I am the President of the non-profit Vascular Research Association. I have written several articles with the principle objective being the improvement of intravenous therapy (see vrassoc.com). I present this information to you in order to better frame my comments on the proposed CDC's guidelines pertaining to intravascular catheters and in the interest of an attempt at full disclosure.

I regret that I was asked to review this draft of the guidelines less than one month ago. Any one of the articles cited in this proposal deserves at least that much time for detailed analysis and review. In light of this limited time for review of the cited data I will primarily critique the theoretical rationale behind some of the proposed guidelines.

I want to thank all of the people who have invested time and effort in writing these proposed guidelines. I hope that my comments and suggestion on the following pages will not be seen as criticism of the draft but instead are seen as helpful comments that can improve the proposed guidelines.

Yours truly,

Guy D. LaRue

Line 6, Regarding; **"Mary Alexander, R.N."** In the interest of full disclosure to the reviewers and users of CDC Guidelines it should be noted that Ms. Alexander receives remuneration from the Infusion Nurses Society. It should be understood that the Infusion Nurses Society derives revenue from the development of standards of practice through the sale of literature pertaining to those standards of practice-standards of practice which are in large part determined by documents such as these proposed CDC Guidelines. In addition, the Infusion Nurses Society derives revenue from the sale of several devices or services that are discussed and even recommended in these CDC Guidelines (for example education programs on insertion of catheters, catheters, cleansers, Chlorhexidine sponges, and catheter securing devices). It is clear that there is a potential conflict of interest with Ms Alexander's input with these guidelines.

It is not my intention to simply point out the conflict of interests that may occur as a result of Ms. Alexander's presence on the CDC committee that developed these guidelines. The bigger issue is that if Ms. Alexander has these potential conflicts of interest then what other disclosure information may be missing concerning other CDC committee members?

56-57, Regarding; **"Educating and training healthcare personnel who insert and maintain catheters"**
This is a difficult issue to address so the vagueness about specific education requirements in these guidelines is understandable. However, it is important to note that the CDC and other health care organizations need to develop detailed and specific educational requirements such as numbers of hours of training. In my experience, I know nurses who have had fewer than three days of education programs or the rough equivalent and then have been considered independent to insert complex intravenous lines in all patients. This is unacceptable. In my practice I require at least 80 hours of initial one on one instruction followed by months of regular assistance on difficult cases followed by permanent mentor availability.

57-58, Regarding; **"Maximal sterile barrier precautions during central venous catheter insertion"**

I assert that the term "maximal" used in the context of the proposed guidelines is more of a slogan than a scientific term. Furthermore I have noted numerous problems with interpreting and implementing this particular guideline.

Webster's Dictionary defines "maximal" as; "highest or greatest possible; of or constituting a maximum." A literal interpretation of "maximal standard barrier precautions" then would mean that each patient receiving central intravenous catheters will have the lines placed in a surgical setting or the equivalent. Even this interpretation of "maximal" sterile barrier precautions is unclear as there are varying degrees of sterile precautions used in surgical settings.

In practice I am witnessing healthcare facilities interpreting "maximal sterile barrier precautions" erratically. Some facilities require all people in a patient's room to wear masks and wash their hands. Some require full body drapes with fenestrated small openings just for the planned catheter insertion site. Some require mask and hair nets for the patients. Other facilities require drapes just large enough to prevent contamination during the insertion. One facility requires every person in the patient's room (including the patient) to wash their hands before the catheter insertion. There is confusion about how to guarantee draped areas as large as a regular hospital bed when inserting catheter in patients on gurneys, in wheelchairs or in infant cribs. I am confused about why the recommendation for maximal sterile barriers applies to peripherally inserted central catheters (PICCs) but not to midline catheters when the only difference in the entire procedure may be a few centimeters difference in catheter length. In my practice, we also place long arm catheters with final tip location in large subclavian veins (with ultrasound verification of that tip position). Do these guidelines for "maximal barrier precautions" apply to these "midclavicular" catheters? Why would this be so if our insertion procedure for midclavicular placements is identical to our procedure for midline placements even to the point that the catheters used are often of the same length as midline catheters and only the insertion site is a few centimeters higher on the arm?

Unless the insertion procedures are to be relegated to surgical suites I suggest that the term "maximal barrier precautions" be removed. I suggest terms such as "enlarged drapes," "sufficiently large drapes," "sufficient drapes," or "large sterile drapes" (as on line 994 for peripheral arterial catheters of these proposed CDC guidelines) be used instead. Those terms clearly project the message that there should be adequate sterile barriers to insure that no item or portion of the insertion procedure be contaminated.

From my previous reviews of studies pertaining to draping the foot of hospital beds in sterile drapes, I have found no solid evidence supporting covering the end of the standard hospital bed with a sterile drape. More importantly, there is no theoretical rationale presented for this requirement. What would that rationale be? Is there evidence that clinicians are contaminating catheters on the foot of the bed when attempting to place those same catheters in necks or arms? Is there evidence that organisms or fomites near the average patient's feet are more virulent or mobile than the any other area of patient's environment?

Again, I regret that I had insufficient time to review the cited references for this particular guideline. However, I am familiar with some of the research on "bundles" by Dr. Peter Pronovost. In those studies, Dr. Pronovost's methodology was to document baseline CRBSI rates and then to measure those same outcomes after implementation of simultaneous changes to several variables related to catheter insertions. Reported small improvements in CRBSI rates in these studies have been asserted to be the result of *all* of the variables within those "bundles." While there is a correlation between those bundles and the outcomes, there is only the weakest evidence of cause and effect. The outcomes may have been evidence of all of the bundled interventions or may have been evidence of the effectiveness of any single item in the bundles. In light of the use of checklists being

filled out by observers, the fact is that the decreased CRBSI rates results may have simply been the result of the Hawthorne effect, the Pygmalion effect or some other bias.

On July 15th, 2009, Dr. Pronovost spoke at a Washington State Hospital Association meeting regarding "Eliminating Hospital Acquired Infections." During a question and answer segment of the seminar I had the opportunity to question Dr. Pronovost about his conclusions in light of the fact that his research was not blinded and did not seem to be consistently based on logic. I specifically pointed out that covering the foot of the bed with a sterile drape did not seem logical when measurements consistently revealed that the head of the average patient's bed and the floor were both nearer insertion sites and probably more contaminated than the clean bedding at the foot of the average patient's bed. Dr. Pronovost replied, (I have to paraphrase some of his response here) that it is true that his studies are not double-blinded but that if he had done that type of science, he would doing research on any one of the parts of the bundle "for years." Dr. Pronovost then said to the audience, "Don't you agree that we had to start somewhere?"

Dr. Pronovost's comments reflect two current misconceptions. The first is that there are certain times when research can or should be rushed. I assert that quality science is a deliberately slow and methodical process precisely to decrease the incidence of invalid conclusions. The second misconception is that somehow we are now entering a new era of "evidenced-based practice" with the implication being that, up until now, there really was no significant effort to decrease CRBSIs. These misconceptions do no favors to the public or to other scientists. Science has been an "evidence-based" since the first scientist. Furthermore, it is simply an incorrect notion that scientists are only now addressing the issue of decreasing CRBSIs. The literature is replete with evidence of dedicated scientists working for years on incremental discoveries that have been implemented over time and that have improved CRBSI rates. It is also untrue that "bundling" is somehow a new concept. In our company and in my practice what is currently called a bundle, we have called (and still call) a "procedure." These procedures have always been based on the best *current* evidence (for example, Dr. Dennis Maki's painstaking and well-controlled research on Chlorhexidine cleanser).

In my experience I have identified numerous instances of actual or potential contamination during neck and long-arm catheter insertions. These instances have included holes in sterile gloves, bare skin between gloves and gown, contamination during removal and donning of gloves, contamination during application or removal of tourniquets, contamination of sterile field by patient movement, contamination of supplies that fall to the floor or touch insertion related equipment such as tables or ultrasound equipment, contamination by sweat or eyeglasses falling from the inserter's face, etceteras. In twenty years however, I have never heard of nor have I experienced a contamination event or near-contamination event secondary to supplies touching the surface of the foot of a patient's bed.

Our equipment supplier has informed me that adding a full body sterile drape to each insertion kit will cost approximately twenty additional dollars. If I were to replicate the entire "bundle" as described in the literature I have reviewed, I would have to pay an

extra person to attend each insertion and monitor the performance of the inserter. Imagine *that* cost added to our healthcare system. It comes down to the question of whether it is logical or financially reasonable to require that certain intravascular catheter devices be placed in an surgical suites or in other situations that desperately try to imitate the maximal sterile conditions found in surgical suites?

The claim that covering the foot of a patient's bed with a sterile drape will reduce CRBSI rates is an extraordinary claim. It is only right for one to ask that such a claim be backed up by extraordinary proof.

60-61, Regarding; **"Using antiseptic/antibiotic impregnated sponge dressings if the rate of infection is high despite adherence to other strategies (i.e., education and training, maximal sterile barrier precautions, and 2% chlorhexidine for skin antisepsis)"**

Again, I did not have time to review the cited references before the deadline for comment period is over but I have read some research on these sponges provided to me by the sales representatives in the past.

The research that I have read is not blinded. Unfortunately the FDA requirements are notoriously lax when it comes to testing the efficacy of medical devices compared to the requirements for most medications. I believe medical devices such as the Chlorhexidine sponge should be subject to at least some forms of blinded studies that the FDA requires of medications.

The Wall Street Journal recently published an article about how less than half of recent FDA studies made it to publication. The reason cited? The results of those studies did not have the desired results. The ones that got published were the studies with the desired results. At one of our facilities caring for long-term critically ill patients we did use Chorhexidine sponge devices as a last resort to eliminate CRBSIs. There was no significant change in the CRBSI rate. I suspect this facility will not publish those results.

Finally, there seems to be error in the logic for recommending Chlorhexidine sponges be used when other actions to lower CRBSI rates have failed. If the sponge has been shown to be a safe and effective agent for preventing infections in the hardest cases then it seems logical to recommend it be used as a first line of defense in all cases.

In our practice we have also found the sponges occasionally macerate fragile skin. In addition these sponges decrease the adhesiveness of the transparent dressing at a point under the dressing where adhesiveness is most important---the point where a dry and intact transparent dressing prevents catheter migration in or out of the insertion site.

71-72, Regarding this guideline; Should be amended to read, **"Category IA. Strongly recommend for implementation and strongly supported by well designed experimental, clinical or epidemiologic studies *as well as a strong theoretical rationale*."** It is clear that fraud in research not only happens but has been relatively common in the past. The need for the addition of the statement "as well as a strong theoretical rationale" should be obvious.

472, Regarding this guideline; Should be amended to read, **"Replace dressings used on short-term dressings every *7 days unless the insertion site is obscured by the dressing and the insertion site cannot be assessed for anomalies. If any dressing obscures the observation of potential insertion site complications, the dressing should be replaced every 24 hours"*** In our practice we use a tightly folded 2x2 gauze over the insertion site as a small pressure tool to impede the bleeding caused by the initial insertion. We also use folded 2x2s around certain catheter hubs to prevent skin breakdown and these are often under the primary transparent dressing (see vrassoc.com for my article in the Journal of Intravenous Nursing on PICC dressings). Neither of these pieces of gauze significantly obscures the vision of the insertion site. This matches the intent of your guidelines on lines 488-490 and would/may help eliminate the odd discrepancy in the guidelines of lines 472-475 regarding the exception for pediatric patients. We have found that changing intact sterile dressings more frequently than 7 days (unless wet, loosened or soiled) actually damages the skin. We have also found that each dressing change increases the likelihood of some outward catheter migration whether in adults or children. The guidelines pertaining to children dressing changes should apply to adult guidelines as well.

Thank you for this opportunity to provide feedback to the proposed CDC guidelines pertaining to the prevention of intravascular catheter-related infections.

Sincerely,
Guy D. LaRue